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My comments address 2 closely related questions: the third point to subpart A in the General Provisions (IV.A.3 in the Docket); and the 2. additional question. Both questions ask for a clarification of , “which records are required by predicate rules” and are therefore required to be part 11 compliant?

Identification of electronic records , relevant to predicate rules , is often hampered because the data is not organized on the computer systems with these records in mind. A common example is the data to be expected in a batch production record. This data can be quite extensive, and some systems must generate a report, which collects this data for printing. This data may even reside on more than one system, further complicating the issue. Electronic records frequently cannot be simply identified which contain the data expected and have the expected features of the record required by the predicate rule.

It is common practice to attempt to apply Part 11 rules to entire databanks when some of the data in the system has relevance to a predicate rule. Where technically possible, it still diverts the attention from the “trees” to the “forest”. Management of a record implies identification of the record as a first step.

Identifying the pertinent data to consider as part of an electronic record should be based upon the purpose of the record. The FDA has previously proposed a classification scheme for records, which they expect to review<sup>12</sup>. This scheme is based upon the use, or purpose, of the record, and it could be very helpful in clarifying electronic records as well. In this scheme, all records that an inspector will be expecting to review can be classified as either: an event, an instruction, or a review. By extrapolation, all predicate rule records can be expected to belong to one of these classes. Examples of such records are given in the illustrations at the end of these comments.

Recordings of events can be quite complex, involving entries by multiple authors, and the batch production record is again a good example to consider for a record, belonging to this class. I believe most of the additional controls for records, required by Part 11, are quite appropriate for these types of records, and this results in additional data to be considered as part of the record, e.g. audit trails and user access. Following the FDA scheme mentioned earlier, instructions for the actions as well as reviews of the event should be considered relevant data, that are at least linked to the event. My concept of the general content of such a record is included in the illustrations.

<sup>1</sup> FDA. **Guide to Inspections of Validation Documentation** (Draft) Oct. 1995.

<sup>2</sup> R.F. Tetzlaff. “GMP Documentation Requirements for Automated Systems: Part II”, **Pharm. Technol.** 16(8), 60-72, 1992.

Instructions and reviews are typically much closer in form to paper documents. They are typically created with a word processor, and the file can be directly considered the electronic record. Although the identification of the record should normally not be a problem with these types, it is useful to consider what Part 11 controls are appropriate. These records are used as reference documents, and controls developed for paper records should be directly applicable, e.g. document versioning. Additional controls relevant to electronic versions to consider are integrity tests, e.g. check sums and data encryption. Here, we see a further benefit from a classification of the records, beyond their direct relevance to the predicate rules. The classification can be used to consider appropriate controls to expect.

Classification of records is an object-oriented approach to records, and therefore is in line with established software practices<sup>3</sup>. The object-oriented approach does not necessarily make a distinction between paper-based and electronic forms of the record or a linked component to a record. The big picture to consider is **all** of the records relevant to a regulated process. Hybrid computer systems can be simply defined. Further, it allows accommodation for future forms of records.

As an example of this, consider modern electronic workflows. The workflow could be the review of a batch production record. It occurs online, and multiple authors enter comments and attach supplementary information to this review. Although this record will satisfy a predicate rule requirement for the review, it has the features of a human recording of an event. The review is now an electronic dynamic event. This record could be expected to have an audit trail and a defined user access. The deciding factor to consider is how the record is used.

<sup>3</sup>P.T. Noble. "Object-Oriented Software Validation", **J. Val. Technol.**, 10(3), 249-256. 2004



